The Honorable Paul D. Tonko
U.S. House of Representatives
Washington, DC 20515

Dear Congressman Tonko:

Thank you for the letter of December 7, 2018, to the Environmental Protection Agency (EPA) concerning per- and polyfluoroalkyl substances (PFAS).

The EPA's New Chemicals Review Program evaluates new chemicals to determine whether they may present unreasonable risk to human health or the environment. Once the EPA's review is complete, submitters may commercialize the chemical substance (subject to any restrictions the Agency may have placed on the manufacture, processing, distribution in commerce or use of the chemical substance) after having submitted a Notice of Commencement (NOC), indicating intent to commence manufacture or import of the chemical. However, it is often the case that submitters either delay or do not choose to commercialize chemicals that have undergone review. Hence, the responses below provide the number of notices for PFAS chemicals for which the EPA received an NOC, as this is the EPA's best indication of whether a PFAS chemical may have entered commerce.

Since 2006, when the PFOA Stewardship Initiative began, the EPA received 148 NOCs for PFAS chemicals that underwent New Chemicals Program review. Of the PFAS chemicals for which EPA has received NOCs, 146 were received prior to June 22, 2016, and 2 after that date.

The Agency also receives exemption notices for chemical substances, which are exempt from full premanufacture notice (PMN) review under TSCA section 5, provided they meet the criteria and maintain certain conditions and controls throughout the duration of the exemption. One such exemption for chemical substances manufactured at 10,000 kg/year or less per year is the Low-Volume Exemption (LVE). Since 2006, the EPA received 328 LVEs for PFAS chemicals and granted 272 of them. Of those granted, 262 were granted prior to June 22, 2016, and 10 after that date.

Regarding new PFAS chemicals entering the market, between 2006 and April 2019, the EPA placed restrictions on new PFAS chemicals through the issuance of 171 orders and 178 significant new use rules (SNURs). As mentioned above, the new chemicals review program evaluates new chemicals and significant new uses of existing chemicals to determine whether they may present unreasonable risk to human health or the environment. When the EPA determines that a chemical substance may present an unreasonable risk, the EPA must issue an

order under TSCA section 5(e). A section 5(e) order typically contains some of the following requirements: limits on specific conditions for manufacturing, processing, distribution or use of the chemical, limits on releases to water and air, toxicity testing, environmental fate testing, worker protection measures (e.g., exposure limits and personal protective equipment), hazard communication language and record-keeping.

The EPA notes that submitters sometimes decide to withdraw their PMN from review once they learn that the EPA has found that the substance may present unreasonable risk and the Agency intends to issue an order under section 5(e). Since 2006, 46 PFAS chemicals have been withdrawn (42 PMN and 2 LVE). Of those withdrawn, 44 were prior to June 22, 2016, and 2 after that date.

Regarding new PFAS chemicals subject to consent orders requiring the development of test data, since 2006, EPA has issued section 5(e) orders that have testing requirements[1] for 157 PFAS chemicals. Of these orders, 34 were issued prior to June 22, 2016, and 122 were issued after that date.

Again, thank you for your letter. If you have further questions, please contact me or our staff may contact Sven-Erik Kaiser in the EPA's Office of Congressional and Intergovernmental Relations at kaiser.sven-erik@epa.gov or at (202) 566-2753.

Sincerely,

Troy M. Lyons
Associate Administrator

[1] Although all orders generally describe testing requirements or potentially useful information, the Agency works with submitters of like chemicals to tailor testing requirements in order to avoid unnecessary vertebrate tests so the number of orders does not necessarily equal the number of test submissions.